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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/548,971

Applicant(s)

LILJEGREN ET AL.

Examiner

David H Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 and 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. § 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. § 112 for claims 1-33 of this application. The provisional application 60/090,649 does not provide support under 35 U.S.C. § 112, first paragraph, for SEQ ID NO: 2 that is encoded by SEQ ID NO: 1, nor does it provide support for an IND1 polynucleotide sequence encoding an IND1 polypeptide of the instant claims. The Examiner has determined that the instant application does have support under 35 U.S.C. § 112, first paragraph, for the instant claims in the parent application 09/339,998, filed 25 June 1999. Hence, for the purpose of applying the prior art in the examination of the instant claims, the priority date of 25 June 1999 will be used.

3. The specification is objected to because on page 1, first paragraph, the sentence beginning with "This application is also related to..." is irrelevant to the claim to priority and should be deleted.

Drawings

4. The Draftsman has objected to the drawings. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required in response to this Office Action, and cannot be held in abeyance. Applicant is required to submit acceptable corrected drawings within the

Art Unit: 1638

time period set in the Office action. See 37 CFR § 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

Claim Objections

5. Claim 8 is objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, the limitation at claim 8 is broader than that of the claim upon which it depends, claim 7. The Examiner suggests that claim 8 be dependent upon claim 5.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 5, 13-16, 20, 24-26, 31 and 32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the limitation "polynucleotide sequence" refers to an arbitrary assignment of letters denoting a sequence of polynucleotides and thus does not state the metes and bounds of the claimed invention. It is suggested that the limitation -- polynucleotide -- be used.

8. Claims 5 and 13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if the limitation "at least 70% identical" is

Art Unit: 1638

referring to the polynucleotide or the polypeptide of the instant claims. Appropriate correction is required.

9. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 5, 9-19 and 29 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims an isolated nucleic acid encoding a polypeptide at least 70% identical to SEQ ID NO: 2, an expression cassette comprising said nucleic acid or a complement thereof, and a plant comprising said expression cassette. In addition, applicant claims that the promoter operably linked to said nucleic acid comprises positions from about 1-2764 or 3362-3856 of SEQ ID NO: 1, and a method of using at claim 29.

Applicant describes a polypeptide having the sequence of SEQ ID NO: 2 that is encoded by the polynucleotide having the sequence of SEQ ID NO: 1, and an expression cassette comprising SEQ ID NO: 1 (pages 36-37 of the Specification).

Applicant does not describe a nucleic acid encoding a polypeptide at least 70% identical to SEQ ID NO: 2, an expression cassette comprising said nucleic acid or a complement thereof, or a plant comprising said expression cassette. Neither does

Art Unit: 1638

applicant describe a nucleic acid comprising positions from about 1-2764 or 3362-3856 of SEQ ID NO: 1 having promoter activity or being a regulatory element.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. See *Fiers* 25 USPQ 2d (CAFC 1993) at 1606 that states "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself".

11. Claims 12, 19 and 29 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims an expression cassette, a transformed plant and a method of delaying fruit dehiscence in a plant comprising a promoter/regulatory element comprising positions from about 1-2764 or 3362-3856 of SEQ ID NO: 1.

Applicant teaches that SEQ ID NO: 1 encodes a bHLH transcription factor (page 36, last paragraph of the specification).

Applicant does not teach that positions from about 1-2764 or 3362-3856 of SEQ ID NO: 1 encode promoter/regulatory elements.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant does not teach what elements of SEQ ID NO: 1 are promoter/regulatory elements. A 2764 or 494 base-pair long region of a DNA fragment that has promoter or regulatory activity cannot predictably be assumed to also have promoter or regulatory activity in a heterologous plant. The art teaches that the use of heterologous promoter/regulatory elements may require additional elements in order for said elements to function as predicted in heterologous plants (see Ellis *et al* 1987, The EMBO Journal 6(1):11-16, specifically the abstract on page 11). Applicant does not teach which elements of SEQ ID NO: 1 function as promoter/regulatory elements, nor does Applicant teach that the claimed elements would properly function in a heterologous plant. Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to screen through a myriad of segments of the claimed DNA fragments of SEQ ID NO: 1 and a myriad of other

promoter elements that may be required for promoter function in a myriad of transformed heterologous plants, as broadly claimed.

12. Claims 20-28 and 30-33 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of delaying fruit dehiscence in *Arabidopsis thaliana*, does not reasonably provide enablement for a method of delaying fruit dehiscence in any plant using the claimed method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a method of delaying fruit dehiscence in a plant comprising introducing into the plant a recombinant expression cassette comprising a promoter operably lined to a polynucleotide sequence encoding an IND1 polypeptide at least about 70% identical to SEQ ID NO: 2 or comprising a polynucleotide sequence at least about 70% identical to positions from about 1-2764 or 3362-3856 of SEQ ID NO: 1.

Applicant teaches a method of delaying fruit dehiscence in *Arabidopsis thaliana* by co-suppression the expression of the endogenous IND1 gene by transforming said plant with a construct comprising a polynucleotide having the sequence of SEQ ID NO: 1 (pages 36-37 of the Specification).

Applicant does not teach a method of delaying fruit dehiscence in a plant other than *Arabidopsis thaliana* in the instant specification.

The teachings of *Wands* are discussed supra.

Art Unit: 1638

Applicant has only provided guidance in the instant specification for the delay of fruit dehiscence in *Arabidopsis thaliana* by co-suppression of the IND1 gene by transforming *Arabidopsis* ^{with} an expression cassette comprising a polynucleotide having the sequence of SEQ ID NO: 1. The art teaches that transforming plants with heterologous genes encoding bHLH transcription factors to produce a desired phenotype, such as the delayed fruit dehiscence of the instant claims, is unpredictable because the heterologous gene product may not regulate all of the required steps needed to produce the desired phenotype (see Quattrocchio *et al* 1998, The Plant Journal 13(4): 475-488, especially the Summary on page 475).

With regards to claims 24 and 26 related to the expression of antisense constructs, the art teaches it is unpredictable what effect that a heterologous antisense construct will have in a transformed plant. Colliver *et al* teaches that expression of a heterologous antisense construct is unpredictable and can lead to unpredicted molecular and biochemical phenotypes (1997, Plant Molecular Biology 35:509-522, see especially the Abstract on page 509).

Hence, it would have required one of ordinary skill at the time of Applicant's invention undue trial and error experimentation to screen through a myriad of transformed plant ^{using} a polynucleotide sequence encoding an IND1 polypeptide at least about 70% identical to SEQ ID NO: 2 or comprising a polynucleotide sequence at least about 70% identical to positions from about 1-2764 or 3362-3856 of SEQ ID NO: 1, or an antisense construct, determine what additional factors may be required to

Art Unit: 1638

produce the claimed phenotype, and determine what combination is required in order to practice the methods as broadly claimed.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-4 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ryan *et al* (Genbank Accession No. AF069299, submitted 9 June 1998). This rejection is made under 102(b) in view of the Examiner's determination that Applicant's effective priority date for the instant claims is 25 June 1999.

Ryan discloses an isolated nucleic acid comprising an IND1 polynucleotide sequence encoding an IND1 polypeptide identical to SEQ ID NO: 2 in gene "F6N15.18" and identifies the encoded polypeptide as a transcription activator Ra. Hence, Ryan has previously disclosed all of the claim limitations.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ryan *et al* (1998) in view of Quattrocchio *et al* (1998).

Applicant claims an isolated nucleic acid encoding a polypeptide at least 70% identical to SEQ ID NO: 2, an expression cassette comprising said nucleic acid or a complement thereof, and a plant comprising said expression cassette.

The teachings of Ryan *et al* are discussed above. In addition, Ryan teaches a polynucleotide having the sequence of SEQ ID NO: 1, specifically from about 1 to about 2764 or from about 3362 to about 3856.

Ryan does not teach an expression cassette comprising the taught isolated nucleic acid, nor does Ryan teach a plant comprising said expression cassette.

Quattrocchio teaches an expression cassette comprising a polynucleotide encoding a bHLH transcription factor and plants transformed therewith (see page 487).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to use the teachings of Ryan to modify the expression cassette and transformed plants of Quattrocchio. Ryan teaches that the encoded polypeptide is likely a transcription factor from the group encompassing bHLH type transcription factors. In addition, it would have been obvious to transform plants with antisense constructs of the taught polynucleotide sequence, especially the homologous plant, in order to suppress expression of the encoded transcription factor. Quattrocchio teaches that it is desirable to transform plants to modify expression of bHLH transcription factors in order to modify plant phenotypes. Given the success of Quattrocchio in producing a transformed plant comprising a recombinant expression cassette comprising a promoter operably linked to a polynucleotide encoding a bHLH type transcription factor, one of skill in the art would have had a reasonable expectation

Art Unit: 1638

of success. The use of other promoters would have been considered obvious, functional equivalents of the CaMV 35S promoter used by Quattrocchio.

Conclusion

17. Claims 20-33 appear to be free of the prior art because it neither suggests nor teaches a method of delaying fruit dehiscence in a plant using the disclosed polynucleotide of SEQ ID NO: 1. The closest prior art is that of Ryan *et al* (Genbank Accession No. AF069299, submitted 9 June 1998), but Ryan does not suggest the claimed method, and Quattrocchio *et al* (1998, The Plant Journal 13(4): 475-488), but Quattrocchio does not suggest a method of delaying fruit dehiscence in a plant.

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.

David H. Kruse, Ph.D.
1 May 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638

